

PATENT COOPERATION TREATY

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NOTIFICATION OF ELECTION

(PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

Commissioner
 US Department of Commerce
 United States Patent and Trademark
 Office, PCT
 2011 South Clark Place Room
 CP2/5C24
 Arlington, VA 22202
 ETATS-UNIS D'AMERIQUE
 in its capacity as elected Office

Date of mailing (day/month/year) 19 March 2001 (19.03.01)	
International application No. PCT/EP00/06916	Applicant's or agent's file reference SCB582PCT
International filing date (day/month/year) 20 July 2000 (20.07.00)	Priority date (day/month/year) 23 July 1999 (23.07.99)
Applicant MALVOLT, Chiara et al	

1. The designated Office is hereby notified of its election made:

☒ in the demand filed with the International Preliminary Examining Authority on:
 12 February 2001 (12.02.01)

☐ in a notice effecting later election filed with the International Bureau on:

2. The election ☒ was
☐ was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No.: (41-22) 740.14.35	Authorized officer Claudio Borton Telephone No.: (41-22) 338.83.38
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PATENT COOPERATION TREATY

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INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference SCB582PCT	FOR FURTHER ACTION see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.	
International application No. PCT/EP 00/ 06916	International filing date (day/month/year) 20/07/2000	(Earliest) Priority Date (day/month/year) 23/07/1999
Applicant CHIESI FARMACEUTICI S.P.A.		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 2 sheets.



It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

- a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.



the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

- b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing:



contained in the international application in written form.



filed together with the international application in computer readable form.



furnished subsequently to this Authority in written form.



furnished subsequently to this Authority in computer readable form.



the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.



the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. ☐ **Certain claims were found unsearchable** (See Box I).

3. ☐ **Unity of invention is lacking** (see Box II).

4. With regard to the **title**,

the text is approved as submitted by the applicant.



the text has been established by this Authority to read as follows:

FORMULATIONS OF STEROID SOLUTIONS FOR INHALATORY ADMINISTRATION

5. With regard to the **abstract**,

the text is approved as submitted by the applicant.



the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is Figure No.

as suggested by the applicant.



because the applicant failed to suggest a figure.



because this figure better characterizes the invention.



None of the figures.

INTERNATIONAL SEARCH REPORT

Inten Application No
PCT/ 00/06916

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61K9/08 A61K9/72 A61K31/58 A61P11/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ, BIOSIS, CHEM ABS Data, MEDLINE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	GB 1 525 181 A (SYNTEX INC) 20 September 1978 (1978-09-20) examples 6,7	1,6
A	WO 96 19969 A (FALK PHARMA GMBH ;OTTERBECK NORBERT (DE); KUEHN REIMUND (DE)) 4 July 1996 (1996-07-04) cited in the application page 3, paragraph 4 -page 6, paragraph 6	1,5

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- *G* document member of the same patent family

Date of the actual completion of the international search

2 January 2001

Date of mailing of the international search report

15/01/2001

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax (+31-70) 340-3016

Authorized officer

Epskamp, S

INTERNATIONAL SEARCH REPORT

Inter. patent family members

Application No



PCT/JP 00/06916

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
GB 1525181 A	20-09-1978	AT 357702 B	25-07-1980
		AT 388376 A	15-12-1979
		AU 506080 B	13-12-1979
		AU 1430176 A	01-12-1977
		CA 1075228 A	08-04-1980
		CA 1083963 A	19-08-1980
		DE 2624924 A	15-12-1977
		DE 2661037 C	06-04-1989
		ES 448220 A	01-11-1977
		FR 2361900 A	17-03-1978
		HK 8580 A	14-03-1980
		IL 49652 A	31-05-1979
		JP 1438219 C	19-05-1988
		JP 51144719 A	13-12-1976
		JP 62047880 B	09-10-1987
		JP 1754517 C	23-04-1993
		JP 4038728 B	25-06-1992
		JP 62281817 A	07-12-1987
		MX 3864 E	26-08-1981
		MY 27580 A	31-12-1980
		NL 7605699 A, B,	30-11-1976
		NZ 180946 A	28-07-1978
		NZ 183905 A	28-07-1978
		PH 13329 A	13-03-1980
		SE 421426 B	21-12-1981
		SE 7605927 A	28-11-1976
		US 4933168 A	12-06-1990
		ZA 7603131 A	25-01-1978
		BE 842192 A	25-11-1976
		PH 13398 A	28-03-1980
WO 9619969 A	04-07-1996	DE 4446891 A	04-07-1996
		AT 168556 T	15-08-1998
		CA 2205305 A	04-07-1996
		DE 59502928 D	27-08-1998
		DK 794767 T	01-02-1999
		EP 0794767 A	17-09-1997
		ES 2120247 T	16-10-1998
		GR 3027632 T	30-11-1998
		JP 10511364 T	04-11-1998
		US 5914122 A	22-06-1999

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference SCB582PCT		FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/EP00/06916	International filing date (day/month/year) 20/07/2000	Priority date (day/month/year) 23/07/1999	
International Patent Classification (IPC) or national classification and IPC A61K9/08			
Applicant CHIESI FARMACEUTICI S.P.A.			
<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 5 sheets, including this cover sheet.</p> <p><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of sheets.</p>			
<p>3. This report contains indications relating to the following items:</p> <ul style="list-style-type: none"> I <input checked="" type="checkbox"/> Basis of the report II <input type="checkbox"/> Priority III <input type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability IV <input type="checkbox"/> Lack of unity of invention V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement VI <input type="checkbox"/> Certain documents cited VII <input type="checkbox"/> Certain defects in the international application VIII <input checked="" type="checkbox"/> Certain observations on the international application 			
Date of submission of the demand 12/02/2001		Date of completion of this report 29.03.2001	
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465		Authorized officer Rinaldi, F Telephone No. +49 89 2399 7360 	

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/EP00/06916

I. Basis of the report

1. This report has been drawn on the basis of *(substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments (Rules 70.16 and 70.17).):*

Description, pages:

1-26 as originally filed

Claims, No.:

1-11 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/EP00/06916

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-11
	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-11
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1-11
	No:	Claims	

2. Citations and explanations
see separate sheet

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:
see separate sheet

Re Item V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1 Reference is made to the following documents:

D1: GB-A-1 525 181 (SYNTEX INC) 20 September 1978 (1978-09-20)

D2: WO 96 19969 A (FALK PHARMA GMBH ;OTTERBECK NORBERT (DE);
KUEHN REIMUND (DE)) 4 July 1996 (1996-07-04) cited in the application

Novelty

2 The subject matter of independent product claim 1, of thereof depending claims 2-10 and of independent method claim 11 fulfills the requirements of Art.33(2) PCT.

2.1 The prior art does not disclose a product **consisting** of:

- 0.01-0.1% of steroid,
- a carrier being a mixture of water to propylene glycol in a ratio 6:4 to 3:7 v/v and
- a pH being adjusted to pH 3.5-5.

2.2 The formulations disclosed in D1, and especially in the examples, comprise additional agents such as emulsifiers, preservatives, PEG-6000. A pH of the formulations around 6.0 is preferred (col.7 l.22).

2.3 The formulations disclosed in the examples of D2 contain at least sodium benzoate and xanthan gum and occasionally also sodium-EDTA. Furthermore, the aerosols solutions disclosed in D2 (examples 7-10) contain water to propylene glycol in a ratio 1:20, several emulsifying agents and sequestrants.

2.4 Accordingly, the process for the production of said product is novel.

Inventive step

3 The subject matter of independent product claim 1, of thereof depending claims 2-10 and of independent method claim 11 fulfills the requirements of Art.33(3) PCT.

3.1 D2 discloses aerosol solutions comprising budesonide having a pH of 3.5-4 (examples 7-10). However, said solutions comprise emulsifying agents and sequestrants. The solutions contain water to propylene glycol in a ratio 1:20.

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/EP00/06916

- 3.2 The objective problem is to provide solutions of steroids without stabilizing agents that are suitable for inhalation and that do not agglomerate during storage.
- 3.3 The solution is provided through
- a carrier consisting of water and propylene glycol in a specific ratio and
 - adjusting the pH of the solution to 3.5-5.0.
- 3.4 This solution of the technical problem is neither disclosed nor suggested in the prior art.
- 3.5 Accordingly, the process for the production of said product involves an inventive step.

Re Item VIII

Certain observations on the international application

The passage on p.6 I.2-16 of the description is not adapted to present claim 1 (Art.6 PCT).